MEDSHAPE
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AUG - 3 2011

510(k) Summary

510(k) Number: K101934

Date Prepared: July 9, 2010

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
MedShape Solutions, Inc.
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Atlanta, Georgia 30318

B. Company Contact:
Don Griffin
Director of Operations
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C. Device Information:
Trade Name: *DynaNail Ankle Nail*
Common Name: Ankle Nail

D. Classification Name: Intramedullary Fixation Rod
HSB 21 CFR 888.3020

E. Predicate Device(s):
DePuy Ace VersaNail™ Intramedullary Fixation Rod, K023115

F. Physical Description:
The proposed DynaNail™ is a sterile, single use titanium Intramedullary Fixation Rod for use in tibiotalocalcaneal fusions. The DynaNail is implanted with a proprietary deployment frame and various lengths of fixation screws. Similar to existing IMFR's, the DynaNail™ provides rigid fixation across the arthrodesis site, and also provides a method of in-line compression through the nail. The nail incorporates a method of compression that is applied during implantation in the same manner as existing nails.

G. Indications for Use:

The *DynaNail*™ Ankle Nail is intended for tibio-talo-calcaneal fusions:

Post-traumatic and degenerative arthritis.
Post-traumatic or primary arthrosis involving both ankle and subtalar joints.
Revision after failed ankle arthrodesis with subtalar involvement.
Failed total ankle arthroplasty.
Non-union ankle arthrodesis.
Rheumatoid hindfoot.
Absent Talus (requiring tibiocalcaneal arthrodesis).
Avascular necrosis of the talus.
Neuroarthropathy or neuropathic ankle deformity.
Neuromuscular disease and severe deformity.
Osteoarthritis.
Charcot Foot.
Previously infected arthrosis, second degree

H. Comparison of Technological Characteristics:

The DynaNail is substantially equivalent in design, function and intended use to the following predicate devices:

DePuy Ace VersaNail™Intramedullary Fixation Rod, K023115

The construction of the DynaNail™ body is equivalent to that of the VersaNail™ device. Both devices are made from Ti-6AL-4V Titanium, have a hollow body with flutes and distal and proximal screw attachment points. The DynaNail™ is offered in a 12 mm diameter, as is the VersaNail™. The DynaNail™ is offered in lengths comparable to those of the VersaNail™.

The DynaNail™ device has an external frame that aligns the IMFR with the tibia and calcaneous and compresses the fusion site before insertion of the distal fixation screws. The DynaNail™ fusion site compression is a function of the compression applied by the external frame and the DynaNail™ Nitinol element.

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Functional performance testing and analysis of the DynaNail™ and VersaNail™ were conducted per ASTM F 1264-03, Standard Specification and Test Methods for Intramedullary Fixation Devices. Four point bend testing was performed on the DynaNail™ and VersaNail™ devices and fixation screws. Fatigue testing was performed on the DynaNail™ and VersaNail™ fixation screws. Nickel release testing and corrosion testing were also performed on the DynaNail™. Analysis of the results demonstrates that the proposed device performs in a substantially equivalent manner to the predicate device.

Don Griffin
Director of Operations

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MedShape Solutions
% Mr. Don Griffin
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

AUG - 3 2011

Re: K101934
Trade/Device Name: DynaNail Ankle Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: July 11, 2011
Received: July 15, 2011

Dear Mr. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

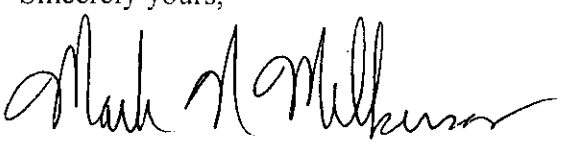
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K101934

Device Name: *DynaNail*™ Ankle Nail

Indications for Use:

The *DynaNail*™ Ankle Nail is intended for tibio-talo-calcaneal fusions:

- Post-traumatic and degenerative arthritis.
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- Neuromuscular disease and severe deformity.
- Osteoarthritis.
- Charcot Foot.
- Previously infected arthrosis, second degree

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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